K002569

DEC 12 2000

XI. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS. July 24, 2000. [Separate Pages]

I.* Submitter: Mike Gamble, Malgam Enterprises Inc., San Francisco, CA 94107; Phone: 415-979-9020.

II. Classification Names and numbers: Syringe, Piston; Code FMF

III. Common/Usual Name: Hypodermic Syringe, piston syringe, insulin syringes

IV. Proprietary Names: GlucoSource™ Insulin Syringes and Malgam™ Single Use Hypodermic Syringes

V. Establishment Registration Number: 2085070

VI. Classification: Syringes were classified by the General Hospital Advisory Committee, as Class II, and are described in CFR 880.5860.

VII. Substantial Equivalence: The GlucoSource™ and Malgam™ Syringe lines are substantially equivalent to the classified device--CFR 880.5860, Piston Syringe. They also are equivalent to several other syringes previously cleared by the 510(k) process as listed below. They are virtually identical with the Ulticare Disposable Syringe cleared under K994230. The Malgam line also contains an insulin syringe which is labeled specifically for insulin. In this regard, it is substantially equivalent to the latest Terumo product (K001474). The Malgam line syringes may be sold with or without needles attached (see BD 980580). The GlucoSource™ and Malgam™ syringes also are substantially equivalent to several other syringes cleared under 510(k)s. Some of these are listed below:

No.	K-Number	Product	Company
1.	K994320 (4230 corrected by hand)	Ulticare Disposable Syringe	Ultimed, Inc.
2.	K000144	Nipro Insulin Syringe	Nipro Medical Corp.
3.	K980580	Becton Dickinson Syringes	Becton Dickinson & Co.
4.	K992802	Terumo U-100 Insulin Syringe	Terumo, Inc.
5.	K991758	Monoject Insulin Syringe	Kendall Co.

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use, for medical purposes for the manual aspiration of fluids, and for the injection of fluids into parts of the body below the surface of the skin. This device is intended for general usage and (when equipped with a specially marked barrel) particularly for the aspiration and injection of insulin.

2. The technological characteristics for this product are the same as those for the predicate devices and those currently on the market except for differences in attaching the needle to the barrel in some cases. It is substantially equivalent to those specially designed to avoid wasting pharmaceuticals. As discussed above, its special characteristics are all equivalent to some of the recently cleared syringes.

3. Descriptive information provided shows that the materials from which Malgam™ syringes are made are substantially equivalent to (nearly identical with some of) those of similar products, used for identical purposes, currently on the market.

4. The FDA "Decision-Making Process" chart was also used and appears in Appendix V.

Malgam's statement that these devices are substantially equivalent to any other device is done solely to comply with the requirements of the Federal Food Drug and Cosmetic Act and is not intended whatsoever to be the basis for a patent infringement action.

END OF SUMMARY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2000

Mr. Micheal L. Gamble
President
Malgam Enterprises, Incorporated
2 Clarence Place, Suite 12
San Francisco, California 94107

Re: K002569
Trade Name: Glucosoure Insulin Syringes and Malgam Single-Use Insulin and Single Use Hypodermic Syringes
Regulatory Class: II and II
Product Code: FMF and FMI
Dated: November 30, 2000
Received: December 1, 2000

Dear Mr. Gamble:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002569

Device Name: GlucoSource Insulin Syringes and Malgam Single-Use Insulin and Single-Use Hypodermic (General Purpose) Syringes

Indications For Use:

Intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002569